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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,074	02/26/2002	Arthur D. Gershowitz	032722-595	4267

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EXAMINER

THOMPSON, MICHAEL M

ART UNIT	PAPER NUMBER
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3763

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DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,074

Applicant(s)

GERSHOWITZ, ARTHUR D.

Examiner

Michael M. Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 7 and 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, drawn to a retrograde cannula, classified in class 604, subclass 167.06.
 - II. Claims 10-14, drawn to a method of inserting a retrograde cannula into a vessel, classified in class 604, subclass 507.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I. and II. are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as for use in the treatment of embolisms through balloon dilatations and treatment of the embolitic site through infusion of medicament or through the introduction of a medical device by lumen or attached to the balloon surface such as a stent.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A. Figures 1-5; B. Figures 6-7 ; C. Figures 8-9

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 appears to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with Alan Kopecki on December 09, 2003 a provisional election was made without traverse to prosecute the invention of Group I, Figures 1-5, claims 1-6 and 8-9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3-4, 7 and 10-14 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 3 and 4 have been withdrawn by the Examiner since claim 3 specifically recites the distal end of the sealing member are affixed to the inner body. This recitation is not found in Figures 1-5. This appears to be germane to Figures 6-7.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Buelna (5,443,449). Buelna teaches a cannula/catheter comprising coaxial inner (18) and outer bodies (27), at least a portion of the inner body being slidable within the outer body, inner body forming an infusion lumen (25) with an outlet adjacent the distal end, a sealing member (50) including proximal and distal ends that are moved away from another in response to axial sliding of the inner body wherein the proximal end of the sealing member is connected to the outer body. He further teaches the outer body including a bulbous portion (16) defined by convexly projecting

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ribs space circumferentially apart (34, 36), the sealing member arranged to surround the bulbous portion the proximal and distal ends of the sealing member affixed to the outer body with an enlargement, and the distal portion of the inner body affixed to the distal portion of the outer body at a location distally of the bulbous portion (Column 4, lines 46-55).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buelna in view of G.C. Kohl (3,397,699) or Blake et al. (3,634,924) or Maria van Erp (6,102,891). Buelna teaches all of the limitations of the claims except for explicitly reciting the sealing member comprising an inflatable balloon, the infusion lumen communicating with an interior of the balloon. Kohl, Blake et al. and Maria van Erp teach a balloon sleeve that acts as a sealing member in communication with an infusion lumen through inflation holes. It would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the sleeve and inner member of Buelna with the balloon sleeve and inflation holes of Kohl, Blake et al. or Maria van Erp to provide for an inflation sleeve/balloon construction well known in the prior art for anchoring a catheter or cannula devices within a vessel and/or for the purpose of occluding the vessel for intervention.

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10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buelna in view of Homm et al. (4,043,338). Buelna teaches all of the limitations of the claims except for explicitly reciting a holding means for holding the inner and outer bodies in selected longitudinal relationship. Homm et al. teaches a holding means for holding the inner and outer bodies in a selected longitudinal relationship slidable with respect to each other to expand the outer body in a region containing longitudinal slits. It would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the inner and outer bodies of Buelna with the holding means as taught by Homm et al. for the purpose of providing a tactile method of actuating the inner and outer tubular members relative to each other to expand the outer member containing longitudinal slits.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buelna in view of Homm et al. as applied to claim 8 above, and further in view of Hillstead (4,885,003) or Lakatos et al. (4,997,419). Buelna and Homm et al. teach all of the limitations of the claims except for explicitly reciting that the holding means comprises the slot including notches for receiving the pin. Both Hillstead and Lakatos et al. teach a pin-in-slot connection similar to the modified pin-in-slot connection of Buelna and Homm et al. with notches for selectively positioning the pin in different positions along the slot or to lock the slot in position at a given location within the slot. It would have been obvious to one of ordinary skill in the art, at the time of invention, to have modified the slot of Buelna and Homm et al. to further include notches as taught by Hillstead or Lakatos et al. for the well known purpose of securing an inner and outer body relative to each other in different axial positions or extensions.

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Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson

Patent Examiner


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MT 

December 10, 2003